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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,115	12/14/2001	Charles L. Sawyers	30435.53USD2	4057

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MANDEL & ADRIANO
55 SOUTH LAKE AVENUE
SUITE 710
PASADENA, CA 91101

EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,115

Applicant(s)

SAWYERS ET AL.

Examiner

Thai-An N Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 21-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' Preliminary Amendment, filed 3/26/02, has been entered.

Note that by Rule 1.126, the claims designated claims 2-15, have been re-numbered claims 21-34.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 21-26, drawn to methods for assessing the effect of a composition or treatment on human prostate cancer using an immune deficient mouse comprising a human prostate cancer xenograft, classified in class 800, subclass 3, 8, 9, 10, 13, 14, 18; class 424, subclass 9.2, 93.21, for example.
- II. Claim 27, drawn to an efficacious composition, classified in class 514, subclass 1+.
- III. Claim 28 drawn to an efficacious treatment, classified in class 514, subclass 1+.
- IV. Claims 29-31, drawn to methods for impairing the progression of human prostate cancer cells providing a composition to a subject comprising human prostate cancer cells, classified in class 800, subclass 3, 8, 9, 10, 13, 14, 18, for example.
- V. Claims 32-34, drawn to methods for impairing the progression of human prostate cancer comprising providing an efficacious treatment to a subject comprising human prostate cancer, classified in class 800, subclass 3, 8, 9, 10, 13, 14, 18, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and either of Inventions II or III are related as process of making and product made. The inventions are distinct if either or both of the

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following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the efficacious treatments can be found in assays that do not require immune deficient mice.

Inventions I and either of Inventions IV or V are mutually exclusive and independent methods. The methods for assessing the effect of a composition or treatment on human prostate cancer using an immune deficient mouse comprising a human prostate cancer xenograft of Invention I are not required for the methods for impairing the progression of human prostate cancer cells providing a composition to a subject comprising human prostate cancer cells of Invention IV or the methods of impairing the progression of human prostate cancer by providing an efficacious treatment of Invention V, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions II and III are to mutually exclusive and independent products. The efficacious composition of Invention II is not required for the efficacious treatment of Invention III. Furthermore, the composition of Invention II can be used in different methods than the treatment of Invention III, for example if Invention II is a protein, it can be used to produce antibodies.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

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shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the efficacious compound of Invention II can be used in different methods, depending on the composition (e.g., if the composition is a protein, it can be used in protein binding assays, for example).

Inventions II and V are mutually exclusive. The efficacious compound of Invention II is not required for the implementation of the methods for impairing the progression of human prostate cancer by providing an efficacious treatment of Invention V, and vice versa.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the efficacious treatment of Invention III can be used in different methods, depending on the structure of the treatment (e.g., if the treatment is a protein, it can be used to produce antibodies, for example).

Inventions IV and V are mutually exclusive and independent methods. The methods for impairing the progression of human prostate cancer cells providing a composition to a subject comprising human prostate cancer cells are not required for

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the implementation of impairing the progression of human prostate cancer comprising providing an efficacious treatment to a subject comprising human prostate cancer of Invention V, and vice versa. Each of the methods requires a materially different and separate protocol, which requires different technical considerations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

Thaian N. Ton
Patent Examiner
Group 1632



DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1600/1630